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| Appl. No. | : 09/470,874 | Confirmation No. 6721 |
| Applicant | : Marc M. Jalisi et al. | |
| Filed | : December 22, 1999 | |
| Title | : COMPOSITE GUIDEWIRE WITH DRAWN AND FILLED TUBE CONSTRUCTION | |
| Art Unit | : 3763 | |
| Examiner | : Mark K. Han | |
| Docket No.: | : ACSG-58267 (G1513USP1) | |
| Customer No. | : 24201 | January 2, 2008 |

SUPPLEMENTAL APPELLANT'S BRIEF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Supplemental Appellant's Brief is being filed in response to the November 1, 2007 Notification of Non-Compliant Appeal Brief. A Request for a One-Month Extension of Time to submit this brief is filed concurrently herewith, along with the appropriate fee for the extension request. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

This brief contains items under the following headings, and in the order set forth below:

- I. REAL PARTY IN INTEREST
- II. RELATED APPEALS AND INTERFERENCES
- III. STATUS OF CLAIMS
- IV. STATUS OF AMENDMENTS
- V. SUMMARY OF THE CLAIMED SUBJECT MATTER
- VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
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- IX. EVIDENCE APPENDIX
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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: Advanced Cardiovascular Systems, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1-15, 17, 19-27 and 29.

B. Status of All of the Claims

Each of pending claims 1-15, 17, 19-27 and 29 stand as finally rejected under 35 U.S.C.

§ 103(a) as obvious over Thome et al. (5,776,080) in view of Fagan et al. (WO 96/25969).

C. Claims on Appeals

The claims on appeal are each of pending claims 1-15, 17, 19-27 and 29.

IV. STATUS OF AMENDMENTS

In the March 14, 2007 Office Action, claims 1-15, 17, 19-27 and 29 were finally rejected under 35 U.S.C. § 103(a). The finally rejected claims are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

As recited in independent claims 1, 8, 26 and 27, the present invention is directed towards a heat treated elongate member or guide wire 10 including a composite elongate core 11 including an inner core 31 formed from precipitation hardened material (See original claims; FIGS. 1-3; p. 8, line 18 et seq.). Moreover, as recited in independent claims 1, 8, 26 and 27, a layer 37 of superelastic material concentrically surrounds the inner core 31 (See p. 9, line 7 et seq.).

In one particular aspect (claim 1), the elongate member 10 includes a second layer 46 concentrically arranged about the layer 37 formed from superelastic material (See p. 9, line 10). Moreover, in other aspects, as recited in independent claims 8, 26 and 27, the elongate member

or guide wire further includes a flexible body or coil 79 disposed about a distal end 28 or distal section 25 of the composite elongate core 11.

Furthermore, in one particular embodiment (claim 8), the composite elongate core 11 of the elongate member 10 includes a precipitation hardenable material comprising at least two materials selected from the grouping consisting of nickel, cobalt, molybdenum, chromium, tungsten and iron (See p. 14, line 16 et seq.). The composite elongate core 11 includes an inner core formed of a precipitation hardenable material 31 concentrically surrounded by a first layer 37 formed of a superelastic material and having a distal section 64 and a proximal section 67 (See p. 10, lines 1-2 and FIG. 1). A flexible body 79 distinct from the first layer 37 at least partially extends over the distal section 64 (See p. 10, lines 4-12 and FIG. 1).

In another particular embodiment (claim 26), the composite elongate core 11 of the elongate member 10 also includes a composite elongate core formed of a precipitation hardenable material 31 concentrically surrounded by a first layer 37 formed of a superelastic material and having a distal section 64 and a proximal section 67 (See p. 10, lines 1-2 and FIG. 1). A flexible coil 79 is disposed at the distal end of the distal section 64 (See p. 10, lines 4-12 and FIG. 1). The precipitation hardened material and the superelastic material extend from the proximal section to at least a part of a length of the flexible coil (See FIG. 1).

In yet another particular embodiment (claim 27), the composite elongate core 11 of the elongate member 10 also includes a composite elongate core formed of a precipitation hardenable material 31 concentrically surrounded by a first layer 37 formed of a superelastic material and having a distal section 64 and a proximal section 67 (See p. 10, lines 1-2 and FIG. 1). A flexible body 79 is disposed at the distal end of the distal section 64 (See p. 10, lines 4-12 and FIG. 1). The distal section includes a tapered distal portion 16 and a proximal portion

proximal to this distal tapered portion 16 (See FIG. 1). The precipitation hardened material and the superelastic material extend from the proximal section 67 of the elongate core to the tapered distal portion 16 of the distal section of the elongate core and continues through at least a length of the flexible body 79 (See FIG. 1).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-15, 17, 19-27 and 29 were improperly rejected under 35 U.S.C. § 103(a) as being obvious over Thome et al. in view of Fagan et al.

VII. ARGUMENT

A. Claims 1-15, 17, 19-27 and 29: § 103(a) as being obvious over Thome et al. in view of Fagan et al.

Claims 1-15, 17, 19-27 and 29 were finally rejected under § 103(a) as being unpatentable over Thome et al. in view of Fagan et al.

In rejecting claim 1, the Examiner states the following:

Regarding claim 1, Thome teaches a heat-treated elongate member comprising a composite core (150), the composite core section including an inner core (154) formed of Hiberco wire, and a layer formed from a superelastic material (178, Nitinol), and a second layer concentrically arranged about the layer formed of superelastic material (176), wherein the layer is arranged about the inner core (See FIG 25) (Col 16 lines 54-end). (March 13, 2007 Office Action, paragraph 2).

The Examiner then further states that "Thome does not teach that the inner core is formed of a precipitation hardened material. Fagan et al. teaches a precipitation hardened material (stainless steel) for use in a medical guide wire (Abstract)" and concluded that "It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan et al. with the guide wire of Thome as an alternate material." Also, in response to the Appellant's previously submitted arguments, the Examiner

argued that "the phrasing 'arranged about' does not have to mean outside or exterior to the superelastic layer, so resin 176 meets this limitation since it is concentric to the superelastic layer."

It is respectfully submitted that the Examiner has not shown that the combined teachings of the Thome et al. and Fagan et al. et al. references teach an elongate member including a composite elongate core having an inner core formed of a precipitation hardened material and a layer formed of a superelastic material, as well as a **second layer concentrically arranged about** the layer formed of superelastic material, as recited in claim 1 and its dependent claims. Notably, the Thome et al. patent does not teach this structure since the metallic layer 178 forms the **outermost surface** of the Thome et al. device and thus, Thome et al. does not disclose or even contemplate a second layer concentrically arranged about a layer formed of superelastic material. In response to the Examiner's statement that the "phrasing 'arranged about' does not have to mean outside or exterior," it is respectfully submitted that one of ordinary skill in the art would indeed understand the phrase to mean **outside** or **exterior**. To wit, one of ordinary skill in the art would not as the Examiner has, conclude that "arranged about" means "within." Therefore, this layer of resin 176 does not meet the claim language of being **arranged about** the superelastic layer 178. The Fagan reference does not disclosed the claimed structure. Accordingly, it is respectfully submitted that independent claim 1 as well as dependent claims are not obvious in view of the cited art for at this reason alone.

With respect to independent claim 8, the Examiner states at page 3, lines 1-5 of the March 13, 2007 Office Action:

Examiner takes the 'flexible body overlying the distal section' to be resin 176. Thome teaches the precipitation hardenable material to be Hiberco 50B, which contains cobalt and iron (and trace elements), and Fagan et al. discloses an alloy of nickel, cobalt, molybdenum and chromium (MP35N, page 17, lines 19).

Further, the Examiner's stated position is that the "resin is the flexible body 'distinct from the first layer.'"

It is respectfully submitted that the cited art does not teach a heat-treated elongate member including a flexible body at least partially overlying a distal section of the composite elongate core formed of a precipitation hardened material concentrically surrounded by a first layer formed of a superelastic material, the flexible body defining structure distinct from the first layer, as is recited in claim 8 and its dependent claims. In rejecting these claims, the Examiner stated that the layer of resin 176 in the Thome device corresponds to the flexible body recited in claim 8. The Examiner has not demonstrated, however, that the layer of resin 176 at least partially **overlays** a first layer formed of a superelastic material as is recited in the claims. Moreover, it is respectfully submitted that the cited art does not teach the subject matter recited in at least dependent claims 20 and 21 which require a second layer disposed at least in part about the first layer (formed from superelastic material), the second layer formed from material similar to the core element material. Thus, it is respectfully submitted that claim 8 and its dependent claims recite subject matter which is patentable over the cited art.

As to independent claim 26, the Examiner states the following at page 3, lines 6-12 of the March 13, 2007 Office action:

Thome further discloses a flexible coil (162, 182) disposed at a distal end of a distal section of the guidewire, wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil. The phrasing 'a distal end of a distal section' is believed to apply to any point at least halfway from the proximal end of the catheter, since any cross-section of the catheter past the halfway point would be 'a distal section' and each section would have a distal end.

As to independent claim 27, the Examiner stated that "Thome further discloses that the distal section is tapered (FIG 27)." Finally, the Examiner stated regarding claims 26 and 27 that "the

phrasing 'a distal end of a distal section' is believed to apply to any point at least halfway from the proximal end of the catheter since any cross-section of the catheter past the halfway point could be 'a distal section' and each section would have a distal end."

It is respectfully submitted that the combined teachings of Thome et al. and Fagan et al. et al. do not render obvious the subject matter recited in independent claims 26 and 27. Significantly, claim 26 recites a guide wire including a flexible coil disposed at a distal end of a distal section of a composite elongate core and independent claim 27 recites a heat-treated elongate member including a flexible body disclosed at a distal end of a distal section of a composite elongate core, and both claims 26 and 27 recite a composite elongate core including an elongate core formed of a precipitation hardenable material concentrically surrounded by a layer formed of a superelastic material, wherein the precipitation hardened material and superelastic material extend through at least the part of a length of the flexible body. It is to be noted that the multi-layered strands 182 of Thome et al., upon which the Examiner relies as defining a flexible coil, are shown in the drawings as terminating proximal of the distal end of the device (See Figures 26 and 27). Furthermore, the multi-layered strands 182 are described in Thome et al. as providing the operative segment 150 (defined in Thome et al. as similar to operative segment 52, which is shown and described as the **proximal most portion** of guide wire 36) with increased pushability and torqueability performance. Increased pushability and torqueability are usually associated with components located at the proximal, not the distal portion of a guide wire. Accordingly, it is submitted that the Thome et al. patent clearly does not teach a guide wire having a flexible coil disposed at a distal end of a distal section as is recited in independent claim 26 or for that matter, a heat-treated elongate member including a flexible body disposed at a distal end of the distal section as recited in independent claim 27.

Furthermore, it is respectfully submitted that the Examiner's asserted definition of "distal end" is misplaced and contrary to the meaning of the term by one of ordinary skill in the art. It is submitted that one of ordinary skill in the art would not conclude, as was suggested by the Examiner, that a distal end of the Thome et al. device could be "any point at least halfway from the proximal end of the catheter." The Examiner provides no basis for this interpretation. Therefore, it is respectfully submitted that claims 26 and 27 also define subject matter which is allowable over the cited art.

It is further submitted that each of independent claims 1, 8, 26 and 27 as well as their respective dependent claims recite subject matter which is patentable over the cited art. As an initial matter, it is respectfully submitted that improper hindsight in conflict with the guidance provided by MPEP 2143 has been employed to modify the teachings of Thome et al. in view of Fagan et al. et al. In fact, the Examiner has only provided a reason for combining the teachings of Thome et al. and Fagan et al. et al. when discussing independent claim 1 and in that regard, the Examiner has merely stated that modifying Thome et al. in view of Fagan et al. et al. would have been obvious to one of ordinary skill in the art because the result would provide "an alternate material." It is respectfully submitted that such reasoning falls short of what is necessary to establish a *prima facie* case of obviousness. Moreover, there is much more structural features to the claims that have to be considered, not just mere interchanging of materials. Appellant submits that the Examiner has thus failed to establish a *prima facie* case of obviousness.

Accordingly, it is respectfully submitted that the Thome et al. and Fagan et al. et al. patents do not render obvious the subject matter recited in claims 1-15, 17, 19-27 and 29. As

such, it is respectfully submitted that each of claims 1-15, 17, 19-27 and 29 were rejected in error.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 1-15, 17, 19-27 and 29. It is respectfully requested that the Board reverse the rejection of the claims and allow the claims 1-15, 17, 19-27 and 29 to pass to issue.

The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,
FULWIDER PATTON LLP

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VIII. CLAIMS

1. (Previously presented): A heat-treated elongate member, comprising:
a composite elongate core;
the composite elongate core including an inner core formed of a precipitation hardened material and a layer formed of a superelastic material; and
a second layer concentrically arranged about the layer formed of the superelastic material;
wherein the layer is arranged concentrically about the inner core.
2. (Original): The elongate member of claim 1 wherein the composite elongate core has a modulus of elasticity of at least 9×10^6 psi.
3. (Original): The elongate member of claim 2 wherein the modulus of elasticity is at least 12×10^6 psi.
4. (Original): The elongate member of claim 3 wherein the modulus of elasticity is at least 15×10^6 psi.
5. (Original): The elongate member of claim 1 wherein the composite elongate core has an ultimate tensile strength of at least 150 ksi.
6. (Original): The elongate member of claim 5 wherein the ultimate tensile strength is at least 180 ksi.
7. (Original): The elongate member of claim 6 wherein the ultimate tensile strength is at least 200 ksi.
8. (Previously presented): A heat-treated elongate member, comprising:
a composite elongate core;

the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a first layer formed of a superelastic material and having a proximal section and distal section;

a flexible body distinct from the first layer at least partially overlying the distal section;
and

wherein the precipitation hardenable material comprises at least two materials selected from the group consisting of nickel, cobalt, molybdenum, chromium, tungsten, and iron.

9. (Previously presented): The elongate member of claim 1 wherein the precipitation hardenable material is precipitation hardenable stainless steel.

10. (Original): The elongate member of claim 9 wherein the precipitation hardenable material is chromium-nickel based single stage martensitic precipitation hardenable stainless steel.

11. (Original): The elongate member of claim 9 wherein the precipitation hardenable stainless steel is essentially nickel free.

12. (Original): The elongate member of claim 9 wherein the precipitation hardenable stainless steel includes less than about 1% nickel.

13. (Original): The elongate member of claim 8 wherein the precipitation hardenable material is a cobalt based precipitation hardenable alloy.

14. (Original): The elongate member of claim 13 wherein the cobalt based alloy further includes nickel, molybdenum and chromium.

15. (Original): The elongate member of claim 14 wherein the alloy further includes less than about 10% by wt. iron.

16. (Canceled)

17. (Previously presented): The elongate member of claim 8 wherein the inner core and the first layer are independently formed.

18. (Canceled)

19. (Previously presented): The elongate member of claim 17 wherein the first layer is formed from superelastic NITINOL.

20. (Previously presented): The elongate member of claim 19 wherein the composite elongate core further includes a second layer disposed at least in part concentrically about the first layer and formed from a material similar to the inner core material.

21. (Previously presented): The elongate member of claim 8 wherein the composite elongate core further includes a second layer portion disposed at least in part about the first layer portion and formed from a material similar to core element material.

22. (Previously presented): The elongate member of claim 8 wherein the elongate member is a guidewire.

23. (Original): The elongate member of claim 22 wherein the composite elongate core includes a distal segment having a distally tapered section with proximal and distal portions, and a distal flexible section, the inner core element being at least partially exposed at the distal flexible section of the distal segment of the composite elongate member.

24. (Original): The elongate member of claim 19 wherein the elongate member is a guidewire.

25. (Original): The elongate member of 24 wherein the composite elongate core includes a distal segment having a distally tapered section with proximal and distal portions, and a distal flexible section, the inner core element being at least partially exposed at the distal flexible section of the distal segment of the composite elongate member, and the first layer

portion being at least substantially exposed at the proximal portion of the distally tapered section of the distal segment of the composite elongate core.

26. (Previously presented): A guide wire, comprising:

a composite elongate core;

the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material and having a proximal section and distal section;

a flexible coil disposed at a distal end of the distal section;

wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil.

27. (Previously presented): A heat-treated elongate member, comprising:

a composite elongate core;

the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material and having a proximal section and distal section;

a flexible body disposed at a distal end of the distal section;

the distal section having a proximal portion and a tapered distal portion; and

wherein the precipitation hardened material and superelastic material extend from the proximal section of the elongate core to the tapered distal portion of the distal section of the elongate core and continuing through at least a part of a length of the flexible body.

28. (Cancel)

29. (Previously presented): The heat-treated elongate member of claim 1, wherein the second layer is formed of the precipitation hardened material.

IX. EVIDENCE APPENDIX

NONE

X. RELATED PROCEEDINGS APPENDIX

NONE

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